MAR 1 3 2013

Section 5. Special 510(k) Summary

Special 510(k) SUMMARY

A summary of Special 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter:	Curative Medical Inc. 3227 Kifer Road Santa Clara, CA 95051 Establishment Number: 3008361782
Company Contact Person: Phone: Fax: Email:	Cuong Tran, Director Research and Development (408) 414-2188 (408) 413-3000 ctran@curativemedical.com
Submission Correspondent: Address: Phone: Email:	Amy McKinney, Regulatory Affairs Consultant 6518 Tamarind Sky Ln, Fulshear, TX 77441 (979) 236-1622 amckinney29@att.net
Device Name:	K Series CPAP System - Curasa CPAP SD
Device Classification Name:	Non-continuous ventilator (BZD) 21 CFR 868.5905
Predicate Devices:	K Series CPAP System (K120285)
Date of Preparation:	February 6, 2013

Device Description:

The K Series CPAP systems are used on adult patients for treatment of obstructive sleep apnea (OSA). The K Series CPAP Systems has 2 commercially available models, Curasa CPAP and Floton CPAP (K120285). This special 510(k) adds the Curasa CPAP SD model to the currently commercially available selection of models. The K series CPAP system provides a stable continuous positive airway pressure (CPAP). The humidifier, which works with all the K Series CPAP Systems, provides warm, humidified air for comfort to the patient, reducing nose and airway dryness. Each K Series CPAP system also includes the following accessories: a power supply, a Patient Air Circuit, and a U-tube connection between CPAP and humidifier.

The Curasa CPAP SD has similar electronic design and software as the Curasa CPAP, except for the addition of a SD card interface and associated software driver. The Curasa CPAP SD can store/read CPAP patient compliance data onto a SD card where it can be viewed by an external PC.

The K Series CPAP system, model Curasa CPAP SD, has the following similarities to the previous cleared predicate device:

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing process

Intended Use:

The K Series CPAP (Continuous Positive Airway Pressure) systems are intended for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment.

Contraindications:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus.
- The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of sinus or middle ear infection. Not for use with patients whose upper airways are by-passed.

Summary of Performance Data and Substantial Equivalence:

The K Series CPAP system, model Curasa CPAP SD, was designed and verified in accordance with the risk analysis and product requirements. All tests were conducted on the new model to establish substantial equivalence to the predicate. The K Series CPAP system, model Curasa CPAP SD, was tested and shown to be compliant with the following standards:

1. EN 60601-1-1:1995 + A1:1993 + A2:1995
   Medical Electrical equipment - Part 1: General requirement for Safety
2. EN 60601-1-2:2001
   Medical Electrical equipment – Part 1-2: General requirement for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests
3. EN ISO 8185:2007
   Respiratory Tract humidifiers for medical use – Particular requirements for respiratory humidifier systems
4. EN ISO 17510:2007
   Sleep Apnoea Breathing therapy – Part 1: Sleep apnoea breathing therapy equipment

The following testing was conducted to demonstrate the performance of K series CPAP system, model Curasa CPAP SD, is as safe and effective as its predicate device in its intended environment:

Design Verification Test	Result
Pressure Testing	Pass
System and User Interface Testing	Pass
IFU Verification Testing	Pass
ESD / EMC / EMI	Pass
Safety Testing (IPX1 / ESD)	Pass
Software Verification Testing	Pass

Test data leveraged from the predicate device includes the following:

- Sound Test
- Reliability Test
- Packaging Test
- Humidity ISO 8185 Test
- VOC and PM2.5 Test
- Biocompatibility Tests

This Special 510(k) submission presents the results of the testing and detailed description to demonstrate that K series CPAP system, model Curasa CPAP SD, is substantially equivalent to the K Series CPAP with heated humidifier systems (K120285), models Curasa CPAP and Floton CPAP.

The table below provides a design comparison of the Curasa CPAP SD to the predicate K Series CPAP with heated humidifier, Curasa model.

Physical Features	Predicate Device - K Series Curasa CPAP (K120285)	K Series Curasa CPAP SD
CPAP Device:		
Device Size (cm)	Curasa: 17 x 11.7 x 9.3	Similar,.17 x 11.8 x 9.7
Weight (kg)	Curasa: 1.4	Same
Humidifier	Yes	Same
Memory Card	No	Yes
Technology	Stable, continuous positive airway pressure	Same
Indications	The K Series CPAP System, is designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment.	Same
Product Use, Transport, Storage :		
Operation (degree Celsius.)	5 to 35	Same

Physical Features	Predicate Device - K Series Curasa CPAP (K120285)	K Series Curasa CPAP SD
Transport & Storage (degree Celsius.)	-20 to 60	Same
Atmosphere Pressure (Operation)	70 to 106 kPa	Same
Standards Compliance		
IEC-60601-1	Yes	Same
IEC-60601-2	Yes	Same
ISO 17510-1	Yes	Same
Mode of Operation	Continuous	Same
AC Power Consumption	90 to 264 VAC, 50-60 Hz, 2A@115VAC and 1A@230VAC	Same
DC Power Consumption	24 VDC, 2.5 A	Same
Type of Protection Against Electric Shock	Class II Equipment	Same
Degree of Protection Against Electric Shock	Type B Applied Part	Same
Degree of Protection Against Ingress of Water	IPX1	Same
Pressure Range (cm H2O)	4-20	Same
Pressure Stability (cm H2O), as measured by ISO 17510-1	4-20 cm H20 +/- 2.0 cm H20 ISO17510 compliant	Same
Maximum Flow (LPM), as measured by ISO 17510-1	35	Same
Compliance		
	IEC-60601-1	Same
	ISO 8185:2007	Same
Power Consumption		
	24VDC derived from A/C power supply	Same
Electrical shock protection:	Class II	Same
Drip Proof Equipment	IPX1	Same
Heater Setting	continuous	Same

The table below provides a comparison of the features of the Curasa CPAP SD to the predicate K Series CPAP with heated humidifier, Curasa model.

Functional Features	Same/Different
Software	Same with the addition of SD card reader driver to Curasa CPAP SD
Hardware Components	Same with the addition of SD card reader circuit board to Curasa CPAP SD
Humidifier	Same
User Interface	Same
Labelling	Same with the addition of handling the SD card to Curasa CPAP SD and new product name
Packaging	Same

Conclusion:

The information and data provided in this Special 510(k) Notification establishes that the K Series CPAP system, model Curasa CPAP SD, is substantially equivalent to the legally marketed predicate device (K120285).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Curative Medical, Incorporated
C/O Ms. Amy E. McKinney, MS, RAC
Regulatory Affairs Consultant
6518 Tamarind Sky Lane
FULSHEAR TX 77441

Re: K123897
Trade/Device Name: K Series CPAP System – Curasa CPAP SD
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 8, 2013
Received: February 11, 2013

Dear Ms. McKinney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~K12XXXX~~ K123897

Device Name: K Series CPAP System – Curasa CPAP SD
Indications For Use:

The K Series CPAP System, is designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg.

It is intended to be used in the home or hospital/institutional environment.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S

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for LS

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123897